




Josh Makower, MD
Chairman & CEO, ExploraMed Development, LLC
Associate Consulting Professor of Medicine, Stanford University
Venture Partner, NEA

THE PERFECT STORM: WHAT LIES AHEAD FOR US MEDICAL TECHNOLOGY?



Agenda

- Background
 - The Acclarent Story
 - The Perfect Storm
 - A Call For Action
- 

My Career So Far..



The Beginning...



An Engineer's View: Sinusitis

Static
Component

BONY
SCAFFOLD

Dynamic
Component

MUCOSAL
SURFACE

MUCO-CILIARY
TRANSPORT &
DRAINAGE

ANATOMIC
FACTORS

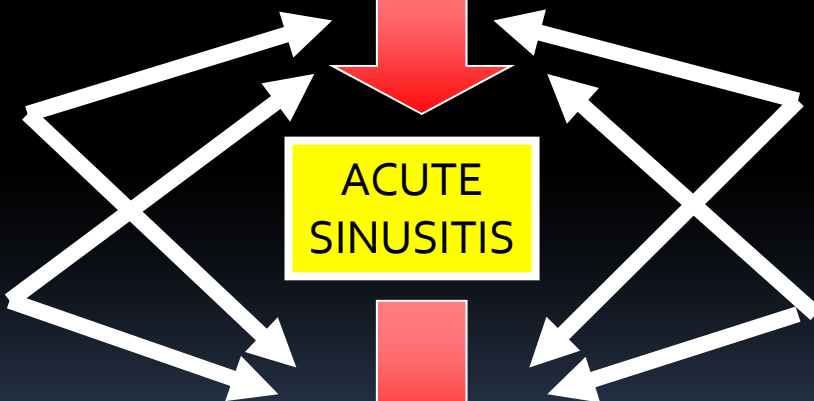
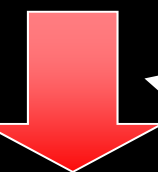
ALLERGIC
FACTORS

MICROBIAL
FACTORS

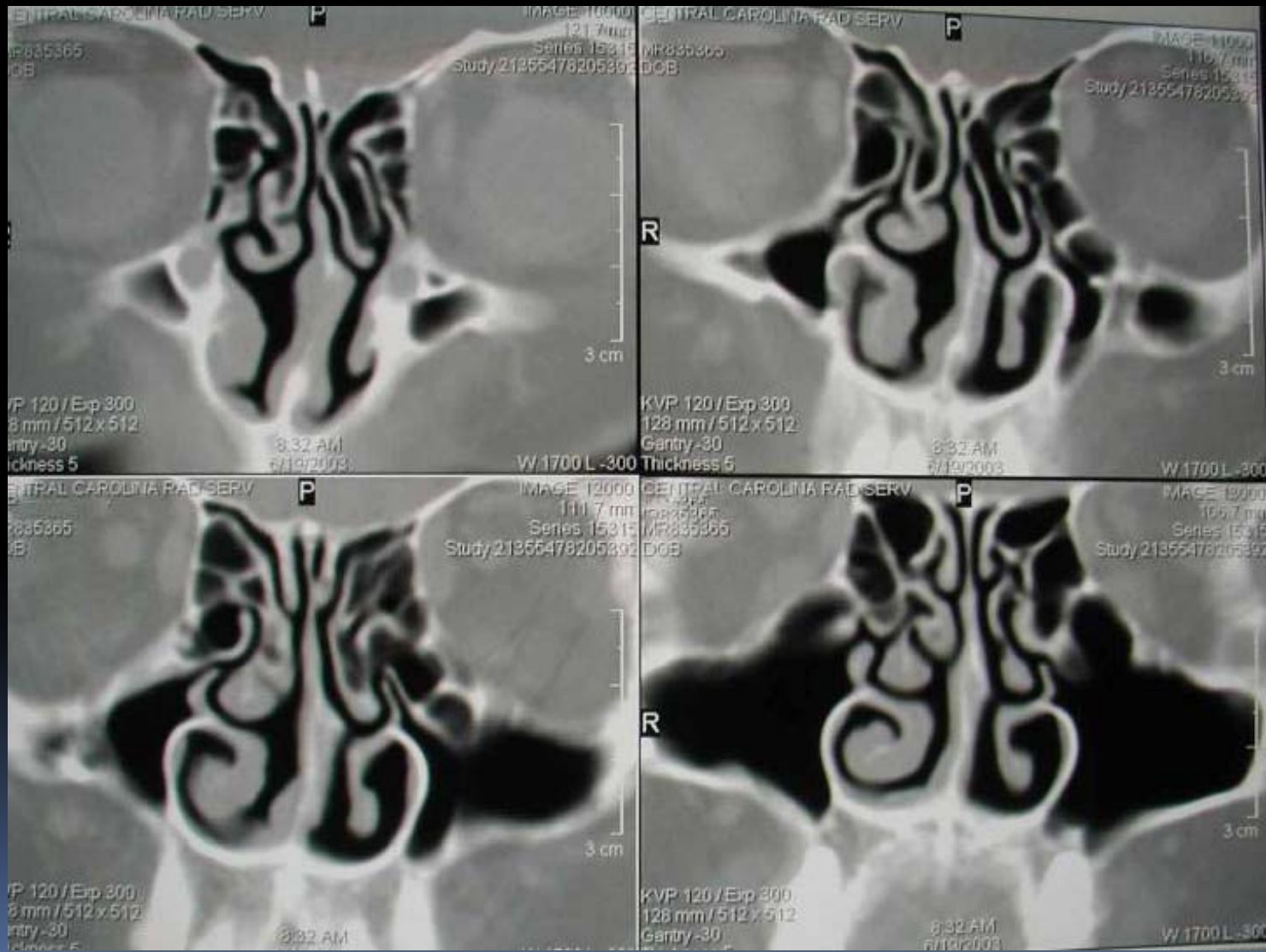
IMMUNE
FACTORS

ACUTE
SINUSITIS

CHRONIC
SINUSITIS



The Aha moment...



The Numbers

- Concept to commercialization – 18 months
- Over 100 patents filings & several licenses
- Over 40 products cleared by the FDA
- Over 30 peer reviewed publications
- Product available in over 40 countries
- Over **100,000** patients treated worldwide
- Profitable, revenue rate >\$100MM/year
- Over 375 jobs created & growing
- Acquired by JNJ for \$785MM

Our challenges?

- Physicians unwillingness to change
- Harsh tactics to undermine the technology
- Lack of understanding of the power and politics within the professional society
- Our intentions being misunderstood
- Our mistakes as we struggled to survive



Did we overcome them?

Not completely...

... that battle still continues...

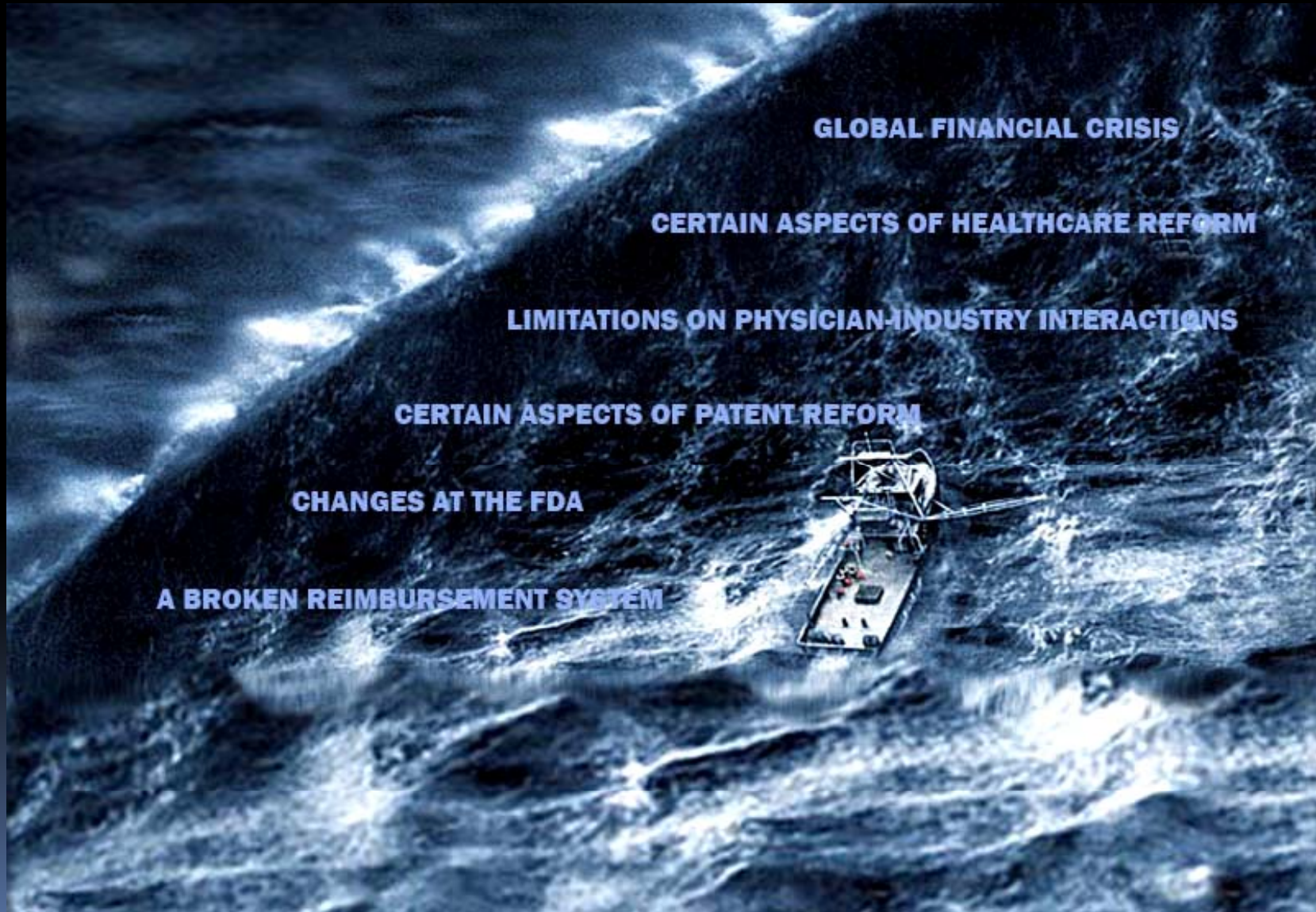
What were the keys to success?

- The idea worked
- FDA process that was predictable
- Investor confidence in our patents
- Readily obtainable financing
- The ability to obtain great clinical advice
- Our doctors ability to perform clinical studies
- A reimbursement scenario flexible enough to incorporate new technology
- We were able to attract truly great people
- We worked really hard and never gave up

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A Perfect Storm?



GLOBAL FINANCIAL CRISIS

CERTAIN ASPECTS OF HEALTHCARE REFORM

LIMITATIONS ON PHYSICIAN-INDUSTRY INTERACTIONS

CERTAIN ASPECTS OF PATENT REFORM

CHANGES AT THE FDA

A BROKEN REIMBURSEMENT SYSTEM

The Financing Climate

- VC financing down nearly \$1B*
 - \$3.4B in 08
 - \$2.5B in 09
- Venture firms “feeding current children” not looking for more to feed
- VC syndicates are breaking
- More reliance on corporate financing
- Good start-ups failing to find capital

*PWC/NVCA MoneyTree Report

The Reimbursement Climate

- Lack of clarity for reimbursement decisions at the CMS level
- Organizations like WellPoint are becoming all powerful
- The CPT process is getting worse
 - More category III codes are being assigned
 - No industry representation on the panel (only BC/BS)
 - Political influence of specialty societies
 - Conflict of interest issues

Healthcare Reform

- Provisions Impacting the Device Industry:
 - Medical Device Excise Tax (aka “Innovation Tax”)
 - \$20B from 2013-2019
 - Begin in 2013 in the form of an excise tax
 - **NOT A TAX ON PROFITS!!**
 - **If tax can't be repealed, we must work together to convince lawmakers to provide relief for smaller companies**
 - Comparative Effectiveness Research (CER)
 - Physician Payment Sunshine Act

Conflict of Interest

- Physician Payment Sunshine Act
- MedTech must work closely with doctors
- Problem: Obsessively focused on monetary compensation to doctors
 - Does a dinner make a doctor forget what's right?
- No acknowledgement of the more powerful conflicts of interest:
 - Political Power
 - Academic Prestige
 - Being 'Right'

FDA Environment

- Disgruntled CDRH staff letter to Congress and WH (2008)
- Press reports and increasing complexity of products have resulted in much lower threshold for risk than in the past (more pre and post-approval requirements)
- FDA Mission:
 - REASONABLE assurance of safety & efficacy
 - AND
 - Promoting Innovation
- Process has become almost completely unpredictable and opaque

A Crushing Wave Is Hovering Over MedTech

- Why should you care?
 - Many administrators believe we've had enough innovation in medicine
 - Many believe we must make cuts on the medtech industry to save healthcare costs
 - They believe innovation in medtech is driving up costs

US Economic Impact

- MedTech Is A Strong Economic Force: *
 - 357,000+ jobs
 - \$21.5B salaries (average salary = \$60K)
 - \$123B product sales
 - Every 1 MTI job generates 4.5 jobs nationwide
 - This multiplier impact created by disposable income connects the MTI to **1.96M** jobs in the US
- But Fragile...
 - 80% MedTech companies employ <50 people**
 - Venture Capital is a key source of funding

** U.S. Dept. of Commerce, International Trade Administration, Invest in America Initiative, Medical Device Sector, 2007

* 2006 "State Impacts of The Medical Technology Industry" The Lewin Group

World Economic Impact

- MedTech Produces 2.7% of the US GDP
- US is the only net exporter medical devices across the world
 - \$5.4B Trade Surplus*
- The impact of patients worldwide returning to work sooner, more productivity

* 2007 World Trade Atlas

MedTech Is Not To Blame For Rising Healthcare Costs

- Easy target, but...
- MedTech revenue comprises approximately 5% of all healthcare spending (>\$2 Trillion)
- Other expenditures have outpaced MedTech spending
 - Percentage of all healthcare spending attributable to MedTech spending has decreased

What Have We Accomplished?

- We have created innovative technologies and procedures to improve the quality of lives and save lives
 - Angioplasty, cardiac pacemakers/defibrillators, pulse oximetry, minimally invasive surgery, tissue sparing cancer therapies, arrhythmia ablation, etc.
- Since 1980,
 - Death rates have declined 16%*
 - Life expectancy has increased 4%*
 - Americans spend 56% less days in the hospital*

* The Value of Investment in Health Care, MEDTAP

What Must Happen?

- Strengthen not weaken our patent system
- Advance pathways for reimbursement of new innovative technologies until they can be compared fairly
- Recognize conflicts throughout the system and manage them better – not exclude them
- FDA process must be reasonable and predictable
- Reinforce how important medical innovation is to people's lives and our economy
- If we repair these issues, we will revive investors, improve the quality of lives and retain talent in our industry to help drive our economy forward

A Call For Action:

- Become a member of the society that represents your interests
- Tell your story to your representatives in Congress DIRECTLY
- Participate in FDA, CMS, etc. hearings
- Recruit others in our industry and the community
- STAY ACTIVELY INVOLVED
- YOUR VOICE MATTERS

The Wave Is Coming...

- You still have time to act....





jmakower@exploramed.com

THANK YOU